510(k) SUMMARY FOR THE PLLA CANNULATED INTERFERENCE SCREW

510k #: K032830

DEC 14 2004

Company: ADVANCED BIOMATERIALS
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Contact: Mr Patrick Janin

Date of submission: September 10th 2003

Name of device:

PLLA cannulated interference screw

Common or usual name:

Bioabsorbable interference screw

Classification:

Smooth or threaded bone fixation fastener: 888.3040

Predicate device:

FMS Cannulated bioabsorbable interference screw (K013685)
Arthrex Bio-interference screw (K971358)

Device description:

The PLLA cannulated interference screw is bio-absorbable sterile single use tapered and has a smooth threaded bone screw, which provides interference fixation of soft tissue grafts and bone-tendon-bone patellar grafts during Anterior Cruciate Ligament repair through arthroscopy or arthrotomy.

Intended use:

The device is cannulated, tapered with a smooth threaded design, which provides interference fixation of soft-tissue grafts and bone-tendon-bone patellar grafts during anterior cruciate ligament repair and reconstruction through arthroscopy or arthrotomy procedures.

The ABS interference screw and predicate device have overall same intended use and design despite some minor modifications which does not affect the reconstruction process.

Both implants are made of similar biopolymer (polylactic acid)

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The screw comes in multiple lengths (20mm to 45mm), multiple diameters (6mm to 12mm) in each length and left and right thread design, resulting in a set of screws adapted to the morphology of the graft and the patient.

Substantial equivalence:

The polymer for the ABS interference screw has similar characteristics than the polymer use for the predicate device (both are poly L,D lactic acid) and is currently use in many devices which have received FDA marketing clearance, and has undergone many in vitro and in vivo testing.

The PLLA cannulated interference screw and the predicate device have the same overall design. In addition, the small differences in design do not affect the use, safety and effectiveness, between the device and the predicate device.

The principal difference in the insertion technique between the ABS PLLA screw and the Arthrex bio-interference screw is the method of attaching the screwdriver to the screw during insertion.

The ABS interference screw is equivalent in material, design and intended use as the predicate device.

Based on these similarities and equivalences we believe our PLLA cannulated interference screw and the Arthrex bio-interference screw K971538 are substantially equivalent for the interference fixation of soft tissue and Bone Tendon Bone graft in the ACL reconstruction through arthroscopy or arthrotomy.

Indications for use:

To provide interference fixation of soft tissue graft and bone-tendon-bone patellar graft during the Anterior Cruciate Ligament repair through arthroscopy or arthrotomy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2004

Mr. Patrick Janin
President
Advanced Biomaterials
265 Route de la Baronne
F-06640 St. Jeannet
France

Re: K032830
Trade/Device Name: PLLA cannulated interference screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: October 19, 2004
Received: October 21, 2004

Dear Mr. Janin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032830

Device name: PLLA cannulated interference screw

Indications For Use:

To provide interference fixation of soft tissue graft and bone-tendon-bone patellar graft during the Anterior Cruciate Ligament repair through arthroscopy or arthrotomy.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032830